

EXHIBIT 18



POLICY STATEMENT

SIDS and Other Sleep-Related Infant Deaths: Expansion of Recommendations for a Safe Infant Sleeping Environment

abstract

FREE

Despite a major decrease in the incidence of sudden infant death syndrome (SIDS) since the American Academy of Pediatrics (AAP) released its recommendation in 1992 that infants be placed for sleep in a non-prone position, this decline has plateaued in recent years. Concurrently, other causes of sudden unexpected infant death that occur during sleep (sleep-related deaths), including suffocation, asphyxia, and entrapment, and ill-defined or unspecified causes of death have increased in incidence, particularly since the AAP published its last statement on SIDS in 2005. It has become increasingly important to address these other causes of sleep-related infant death. Many of the modifiable and nonmodifiable risk factors for SIDS and suffocation are strikingly similar. The AAP, therefore, is expanding its recommendations from focusing only on SIDS to focusing on a safe sleep environment that can reduce the risk of all sleep-related infant deaths, including SIDS. The recommendations described in this policy statement include supine positioning, use of a firm sleep surface, breastfeeding, room-sharing without bed-sharing, routine immunizations, consideration of using a pacifier, and avoidance of soft bedding, overheating, and exposure to tobacco smoke, alcohol, and illicit drugs. The rationale for these recommendations is discussed in detail in the accompanying “Technical Report—SIDS and Other Sleep-Related Infant Deaths: Expansion of Recommendations for a Safe Infant Sleeping Environment,” which is included in this issue of *Pediatrics* (www.pediatrics.org/cgi/content/full/128/5/e1341). *Pediatrics* 2011;128:1030–1039

INTRODUCTION

Sudden infant death syndrome (SIDS) is a cause assigned to infant deaths that cannot be explained after a thorough case investigation, including a scene investigation, autopsy, and review of the clinical history.¹ Sudden unexpected infant death (SUID), also known as sudden unexpected death in infancy, is a term used to describe any sudden and unexpected death, whether explained or unexplained (including SIDS), that occurs during infancy. After case investigation, SUIDs can be attributed to suffocation, asphyxia, entrapment, infection, ingestions, metabolic diseases, arrhythmia-associated cardiac channelopathies, and trauma (accidental or nonaccidental). The distinction between SIDS and other SUIDs, particularly those that occur during an observed or unobserved sleep period (sleep-related infant deaths), such as ac-

TASK FORCE ON SUDDEN INFANT DEATH SYNDROME

KEY WORDS

SIDS, sudden infant death, infant mortality, sleep position, bed-sharing, tobacco, pacifier, immunization, bedding, sleep surface

ABBREVIATIONS

SIDS—sudden infant death syndrome
SUID—sudden unexpected infant death
AAP—American Academy of Pediatrics

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TABLE 1 Summary and Strength of Recommendations

Level A recommendations

- Back to sleep for every sleep
- Use a firm sleep surface
- Room-sharing without bed-sharing is recommended
- Keep soft objects and loose bedding out of the crib
- Pregnant women should receive regular prenatal care
- Avoid smoke exposure during pregnancy and after birth
- Avoid alcohol and illicit drug use during pregnancy and after birth
- Breastfeeding is recommended
- Consider offering a pacifier at nap time and bedtime
- Avoid overheating
- Do not use home cardiorespiratory monitors as a strategy for reducing the risk of SIDS
- Expand the national campaign to reduce the risks of SIDS to include a major focus on the safe sleep environment and ways to reduce the risks of all sleep-related infant deaths, including SIDS, suffocation, and other accidental deaths; pediatricians, family physicians, and other primary care providers should actively participate in this campaign

Level B recommendations

- Infants should be immunized in accordance with recommendations of the AAP and Centers for Disease Control and Prevention
- Avoid commercial devices marketed to reduce the risk of SIDS
- Supervised, awake tummy time is recommended to facilitate development and to minimize development of positional plagiocephaly

Level C recommendations

- Health care professionals, staff in newborn nurseries and NICUs, and child care providers should endorse the SIDS risk-reduction recommendations from birth
- Media and manufacturers should follow safe-sleep guidelines in their messaging and advertising
- Continue research and surveillance on the risk factors, causes, and pathophysiological mechanisms of SIDS and other sleep-related infant deaths, with the ultimate goal of eliminating these deaths entirely

These recommendations are based on the US Preventive Services Task Force levels of recommendation (www.uspreventiveservicestaskforce.org/uspstf/grades.htm).

Level A: Recommendations are based on good and consistent scientific evidence (ie, there are consistent findings from at least 2 well-designed, well-conducted case-control studies, a systematic review, or a meta-analysis). There is high certainty that the net benefit is substantial, and the conclusion is unlikely to be strongly affected by the results of future studies.

Level B: Recommendations are based on limited or inconsistent scientific evidence. The available evidence is sufficient to determine the effects of the recommendations on health outcomes, but confidence in the estimate is constrained by such factors as the number, size, or quality of individual studies or inconsistent findings across individual studies. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.

Level C: Recommendations are based primarily on consensus and expert opinion.

cidental suffocation, is challenging and cannot be determined by autopsy alone. Scene investigation and review of the clinical history are also required. Many of the modifiable and nonmodifiable risk factors for SIDS and suffocation are strikingly similar. This document focuses on the subset of SUIDs that occurs during sleep.

The recommendations outlined herein were developed to reduce the risk of SIDS and sleep-related suffocation, asphyxia, and entrapment among infants in the general population. As defined by epidemiologists, risk refers to the probability that an outcome will occur given the presence of a particular factor or set of factors. Although all of the 18 recommendations cited below are intended for parents, health care providers, and others who care for infants, the last 4 recommendations are also directed toward health policy

makers, researchers, and professionals who care for or work on behalf of infants. In addition, because certain behaviors, such as smoking, can increase risk for the infant, some recommendations are directed toward women who are pregnant or may become pregnant in the near future.

Table 1 summarizes the major recommendations, along with the strength of each recommendation. It should be noted that there have been no randomized controlled trials with regards to SIDS and other sleep-related deaths; instead, case-control studies are the standard.

Because most of the epidemiologic studies that established the risk factors and on which these recommendations are based include infants up to 1 year of age, these recommendations for sleep position and the sleep envi-

ronment should be used consistently for infants up to 1 year of age. Individual medical conditions might warrant that a physician recommend otherwise after weighing the relative risks and benefits.

For the background literature review and data analyses on which this policy statement and recommendations are based, please refer to the accompanying “Technical Report—SIDS and Other Sleep-Related Infant Deaths: Expansion of Recommendations for a Safe Infant Sleeping Environment,” available in the online version of this issue of *Pediatrics*.²

RECOMMENDATIONS

1. Back to sleep for every sleep—To reduce the risk of SIDS, infants should be placed for sleep in a supine position (wholly on the back) for every

sleep by every caregiver until 1 year of life.³⁻⁷ Side sleeping is not safe and is not advised.^{4,6}

- a. The supine sleep position does not increase the risk of choking and aspiration in infants, even those with gastroesophageal reflux, because they have protective airway mechanisms.^{8,9} Infants with gastroesophageal reflux should be placed for sleep in the supine position for every sleep, with the rare exception of infants for whom the risk of death from complications of gastroesophageal reflux is greater than the risk of SIDS (ie, those with upper airway disorders, for whom airway protective mechanisms are impaired),¹⁰ including infants with anatomic abnormalities such as type 3 or 4 laryngeal clefts who have not undergone antireflux surgery. Elevating the head of the infant's crib while the infant is supine is not recommended.¹¹ It is ineffective in reducing gastroesophageal reflux; in addition, it might result in the infant sliding to the foot of the crib into a position that might compromise respiration.
- b. Preterm infants are at increased risk of SIDS,^{12,13} and the association between prone sleep position and SIDS among low birth weight infants is equal to, or perhaps even stronger than, the association among those born at term.¹⁴ Preterm infants and other infants in the NICU should be placed in the supine position for sleep as soon as the infant is medically stable and significantly before the infant's anticipated

discharge, by 32 weeks' postmenstrual age.¹⁵ NICU personnel should endorse safe-sleeping guidelines with parents of infants from the time of admission to the NICU.

- c. There is no evidence that placing infants on the side during the first few hours of life promotes clearance of amniotic fluid and decreases the risk of aspiration. Infants in the newborn nursery and infants who are rooming in with their parents should be placed in the supine position as soon as they are ready to be placed in the bassinet.
 - d. Although data to make specific recommendations as to when it is safe for infants to sleep in the prone or side position are lacking, studies that have established prone and side sleeping as risk factors for SIDS include infants up to 1 year of age. Therefore, infants should continue to be placed supine until 1 year of age. Once an infant can roll from supine to prone and from prone to supine, the infant can be allowed to remain in the sleep position that he or she assumes.
2. Use a firm sleep surface—A firm crib mattress, covered by a fitted sheet, is the recommended sleeping surface to reduce the risk of SIDS and suffocation.
 - a. A crib, bassinet, or portable crib/play yard that conforms to the safety standards of the Consumer Product Safety Commission and ASTM International (formerly the American Society for Testing and Materials) is recommended.¹⁶ In addition, parents and providers should

check to make sure that the product has not been recalled. Cribs with missing hardware should not be used, and the parent or provider should not attempt to fix broken components of a crib, because many deaths are associated with cribs that are broken or have missing parts (including those that have presumably been fixed). Local organizations throughout the United States can help to provide low-cost or free cribs or play yards for families with financial constraints.

- b. Only mattresses designed for the specific product should be used. Mattresses should be firm and maintain their shape even when the fitted sheet designated for that model is used, such that there are no gaps between the mattress and the side of the crib, bassinet, portable crib, or play yard. Pillows or cushions should not be used as substitutes for mattresses or in addition to a mattress. Soft materials or objects such as pillows, quilts, comforters, or sheepskins, even if covered by a sheet, should not be placed under a sleeping infant. If a mattress cover to protect against wetness is used, it should be tightly fitting and thin.
- c. Infants should not be placed for sleep on beds because of the risk of entrapment and suffocation.^{17,18} In addition, portable bed rails should not be used with infants because of the risk of entrapment and strangulation.
- d. The infant should sleep in an area free of hazards, such

as dangling cords, electric wires, and window-covering cords, because they might present a strangulation risk.

- e. Sitting devices, such as car safety seats, strollers, swings, infant carriers, and infant slings, are not recommended for routine sleep in the hospital or at home.^{19–23} Infants who are younger than 4 months are particularly at risk, because they might assume positions that can create risk of suffocation or airway obstruction. When infant slings and cloth carriers are used for carrying, it is important to ensure that the infant's head is up and above the fabric, the face is visible, and that the nose and mouth are clear of obstructions.²⁴ After nursing, the infant should be repositioned in the sling so that the head is up, is clear of fabric, and is not against the adult's body or the sling. If an infant falls asleep in a sitting device, he or she should be removed from the product and moved to a crib or other appropriate flat surface as soon as is practical. Car safety seats and similar products are not stable on a crib mattress or other elevated surfaces.^{25–29}
3. Room-sharing without bed-sharing is recommended—There is evidence that this arrangement decreases the risk of SIDS by as much as 50%.^{5,7,30,31} In addition, this arrangement is most likely to prevent suffocation, strangulation, and entrapment that might occur when the infant is sleeping in an adult bed.
 - a. The infant's crib, portable crib, play yard, or bassinet

should be placed in the parents' bedroom close to the parents' bed. This arrangement reduces SIDS risk and removes the possibility of suffocation, strangulation, and entrapment that might occur when the infant is sleeping in the adults' bed. It also allows close parental proximity to the infant and facilitates feeding, comforting, and monitoring of the infant.

- b. Devices promoted to make bed-sharing "safe" (eg, in-bed co-sleepers) are not recommended.
- c. Infants may be brought into the bed for feeding or comforting but should be returned to their own crib or bassinet when the parent is ready to return to sleep.^{6,32} Because of the extremely high risk of SIDS and suffocation on couches and armchairs,^{3,5,6,31,32} infants should not be fed on a couch or armchair when there is a high risk that the parent might fall asleep.
- d. Epidemiologic studies have not demonstrated any bed-sharing situations that are protective against SIDS or suffocation. Furthermore, not all risks associated with bed-sharing, such as parental fatigue, can be controlled. Therefore, the American Academy of Pediatrics (AAP) does not recommend any specific bed-sharing situations as safe. Moreover, there are specific circumstances that, in epidemiologic studies, substantially increase the risk of SIDS or suffocation while bed-sharing. In particular, it should be stressed to

parents that they avoid the following situations at all times:

- i. Bed-sharing when the infant is younger than 3 months, regardless of whether the parents are smokers or not.^{5,7,31–34}
- ii. Bed-sharing with a current smoker (even if he or she does not smoke in bed) or if the mother smoked during pregnancy.^{5,6,34–36}
- iii. Bed-sharing with someone who is excessively tired.
- iv. Bed-sharing with someone who has or is using medications (eg, certain antidepressants, pain medications) or substances (eg, alcohol, illicit drugs) that could impair his or her alertness or ability to arouse.^{7,37}
- v. Bed-sharing with anyone who is not a parent, including other children.³
- vi. Bed-sharing with multiple persons.³
- vii. Bed-sharing on a soft surface such as a waterbed, old mattress, sofa, couch, or armchair.^{3,5,6,31,32}
- viii. Bed-sharing on a surface with soft bedding, including pillows, heavy blankets, quilts, and comforters.^{3,38}
- e. It is prudent to provide separate sleep areas and avoid co-bedding for twins and higher-order multiples in the hospital and at home.³⁹
4. Keep soft objects and loose bedding out of the crib to reduce the risk of SIDS, suffocation, entrapment, and strangulation.
 - a. Soft objects, such as pillows and pillow-like toys, quilts, comfort-

ers, and sheepskins, should be kept out of an infant's sleeping environment.^{40–45}

- b. Loose bedding, such as blankets and sheets, might be hazardous and should not be used in the infant's sleeping environment.^{3,6,46–51}
 - c. Because there is no evidence that bumper pads or similar products that attach to crib slats or sides prevent injury in young infants and because there is the potential for suffocation, entrapment, and strangulation, these products are not recommended.^{52,53}
 - d. Infant sleep clothing that is designed to keep the infant warm without the possible hazard of head covering or entrapment can be used.
5. Pregnant women should receive regular prenatal care—There is substantial epidemiologic evidence linking a lower risk of SIDS for infants whose mothers obtain regular prenatal care.^{54–57}
 6. Avoid smoke exposure during pregnancy and after birth—Both maternal smoking during pregnancy and smoke in the infant's environment after birth are major risk factors for SIDS.
 - a. Mothers should not smoke during pregnancy or after the infant's birth.^{1,58–61}
 - b. There should be no smoking near pregnant women or infants. Encourage families to set strict rules for smoke-free homes and cars and to eliminate secondhand tobacco smoke from all places in which children and other nonsmokers spend time.^{62,63}
 - c. The risk of SIDS is particularly high when the infant bed-

shares with an adult smoker.^{5,6,34–36}

7. Avoid alcohol and illicit drug use during pregnancy and after birth—There is an increased risk of SIDS with prenatal and postnatal exposure to alcohol or illicit drug use.
 - a. Mothers should avoid alcohol and illicit drugs periconceptionally and during pregnancy.^{64–70}
 - b. Parental alcohol and/or illicit drug use in combination with bed-sharing places the infant at particularly high risk of SIDS.^{7,37}
8. Breastfeeding is recommended.
 - a. Breastfeeding is associated with a reduced risk of SIDS.^{71–73} If possible, mothers should exclusively breastfeed or feed with expressed human milk (ie, not offer any formula or other non-human milk-based supplements) for 6 months, in alignment with recommendations of the AAP.⁷⁴
 - b. The protective effect of breastfeeding increases with exclusivity.⁷³ However, any breastfeeding has been shown to be more protective against SIDS than no breastfeeding.⁷³
9. Consider offering a pacifier at nap time and bedtime—Although the mechanism is yet unclear, studies have reported a protective effect of pacifiers on the incidence of SIDS.^{3,7,32} The protective effect persists throughout the sleep period, even if the pacifier falls out of the infant's mouth.
 - a. The pacifier should be used when placing the infant for sleep. It does not need to be

reinserted once the infant falls asleep. If the infant refuses the pacifier, he or she should not be forced to take it. In those cases, parents can try to offer the pacifier again when the infant is a little older.

- b. Because of the risk of strangulation, pacifiers should not be hung around the infant's neck. Pacifiers that attach to infant clothing should not be used with sleeping infants.
 - c. Objects such as stuffed toys, which might present a suffocation or choking risk, should not be attached to pacifiers.
 - d. For breastfed infants, delay pacifier introduction until breastfeeding has been firmly established,⁷⁴ usually by 3 to 4 weeks of age.
 - e. There is insufficient evidence that finger-sucking is protective against SIDS.
10. Avoid overheating—Although studies have revealed an increased risk of SIDS with overheating,^{75–78} the definition of overheating in these studies varied. Therefore, it is difficult to provide specific room-temperature guidelines for avoiding overheating.
 - a. In general, infants should be dressed appropriately for the environment, with no more than 1 layer more than an adult would wear to be comfortable in that environment.
 - b. Parents and caregivers should evaluate the infant for signs of overheating, such as sweating or the infant's chest feeling hot to the touch.
 - c. Overbundling and covering of the face and head should be avoided.⁷⁹

- d. There is currently insufficient evidence to recommend the use of a fan as a SIDS risk-reduction strategy.
11. Infants should be immunized in accordance with recommendations of the AAP and the Centers for Disease Control and Prevention—There is no evidence that there is a causal relationship between immunizations and SIDS.⁸⁰ Indeed, recent evidence suggests that immunization might have a protective effect against SIDS.^{81–83} Infants should also be seen for regular well-child checks in accordance with AAP recommendations.
 12. Avoid commercial devices marketed to reduce the risk of SIDS—These devices include wedges, positioners, special mattresses, and special sleep surfaces. There is no evidence that these devices reduce the risk of SIDS or suffocation or that they are safe.
 - a. The AAP concurs with the US Food and Drug Administration and Consumer Product Safety Commission that manufacturers should not claim that a product or device protects against SIDS unless there is scientific evidence to that effect.
 13. Do not use home cardiorespiratory monitors as a strategy to reduce the risk of SIDS—Although cardiorespiratory monitors can be used at home to detect apnea, bradycardia, and, when pulse oximetry is used, decreases in oxyhemoglobin saturation, there is no evidence that use of such devices decreases the incidence of SIDS.^{84–87} They might be of value for selected infants but should not be used routinely.
- There is also no evidence that routine in-hospital cardiorespiratory monitoring before discharge from the hospital can identify newborn infants at risk of SIDS.
14. Supervised, awake tummy time is recommended to facilitate development and to minimize development of positional plagiocephaly.
 - a. Although there are no data to make specific recommendations as to how often and how long it should be undertaken, supervised, awake tummy time is recommended on a daily basis, beginning as early as possible, to promote motor development, facilitate development of the upper body muscles, and minimize the risk of positional plagiocephaly.⁸⁸
 - b. Diagnosis, management, and other prevention strategies for positional plagiocephaly, such as avoidance of excessive time in car safety seats and changing the infant's orientation in the crib, are discussed in detail in the recent AAP clinical report on positional skull deformities.⁸⁸
 15. Health care professionals, staff in newborn nurseries and neonatal intensive care nurseries, and child care providers should endorse the SIDS risk-reduction recommendations from birth.^{89–91}
 - a. Staff in NICUs should model and implement all SIDS risk-reduction recommendations as soon as the infant is clinically stable and significantly before anticipated discharge.
 - b. Staff in newborn nurseries should model and implement these recommendations beginning at birth and well before anticipated discharge.
 - c. All physicians, nurses, and other health care professionals should receive education on safe infant sleep.
 - d. All child care providers should receive education on safe infant sleep and implement safe sleep practices. It is preferable that they have written policies.
 16. Media and manufacturers should follow safe-sleep guidelines in their messaging and advertising.

Media exposures (including movie, television, magazines, newspapers, and Web sites), manufacturer advertisements, and store displays affect individual behavior by influencing beliefs and attitudes.^{89,91} Media and advertising messages contrary to safe-sleep recommendations might create misinformation about safe sleep practices.⁹²
 17. Expand the national campaign to reduce the risks of SIDS to include a major focus on the safe sleep environment and ways to reduce the risks of all sleep-related infant deaths, including SIDS, suffocation, and other accidental deaths. Pediatricians, family physicians, and other primary care providers should actively participate in this campaign.
 - a. Public education should continue for all who care for infants, including parents, child care providers, grandparents, foster parents, and babysitters, and should include strategies for overcoming barriers to behavior change.
 - b. The campaign should continue to have a special focus

on the black and American Indian/Alaskan Native populations because of the higher incidence of SIDS and other sleep-related infant deaths in these groups.

- c. The campaign should specifically include strategies for increasing breastfeeding while decreasing bed-sharing and eliminating tobacco smoke exposure.
 - d. These recommendations should be introduced before pregnancy and ideally in secondary school curricula for both boys and girls. The importance of maternal preconceptional health and avoidance of substance use (including alcohol and smoking) should be included in this training.
 - e. Safe-sleep messages should be reviewed, revised, and reissued at least every 5 years to address the next generation of new parents and products on the market.
18. Continue research and surveillance on the risk factors, causes, and pathophysiological mechanisms of SIDS and other sleep-related infant deaths, with the ul-

timate goal of eliminating these deaths entirely.

- a. Education campaigns need to be evaluated, and innovative intervention methods need to be encouraged and funded.
- b. Continued research and improved surveillance on the etiology and pathophysiological basis of SIDS should be funded.
- c. Standardized protocols for death-scene investigations should continue to be implemented. Comprehensive autopsies that include full external and internal examination of all major organs and tissues (including the brain), complete radiographs, metabolic testing, and toxicology screening should be performed. Training about how to conduct comprehensive death-scene investigation offered to medical examiners, coroners, death-scene investigators, first responders, and law enforcement should continue, and resources for maintaining training and conduct of these investigations need to be allocated. In addition, child death reviews, with involvement of pediatricians

and other primary care providers, should be supported and funded.

- d. Improved and widespread surveillance of SIDS and SUID cases should be implemented and funded.
- e. Federal and private funding agencies should remain committed to all aspects of the aforementioned research.

LEAD AUTHOR

Rachel Y. Moon, MD

TASK FORCE ON SUDDEN INFANT DEATH SYNDROME, 2010–2011

Rachel Y. Moon, MD, Chairperson

Robert A. Darnall, MD

Michael H. Goodstein, MD

Fern R. Hauck, MD, MS

CONSULTANTS

Marian Willinger, PhD – *Eunice Kennedy Shriver National Institute for Child Health and Human Development*

Carrie K. Shapiro-Mendoza, PhD, MPH – *Centers for Disease Control and Prevention*

STAFF

James Couto, MA

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